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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/426,111 | 10/22/1999 | J. ROBERT MITCHELL | 10991572-1 | 1439 |

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| EXAMINER |
|---|
| BEX, PATRICIA K |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1743 | 15 |

DATE MAILED: 02/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/426,111 | MITCHELL, J. ROBERT | |
| | Examiner | Art Unit | |
| | P. Kathryn Bex | 1743 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *09 December 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *2-11,30-32 and 42-47* is/are pending in the application.

4a) Of the above claim(s) *12-28, 33-41* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-11,30-32 and 42-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

1. As discussed in the Advisory action, mailed September 24, 2002, the previous rejections under 35 U.S.C. 102(b) and 103(a) Winkler *et al* (USP 5,384,261) have been withdrawn. Additionally, in view of the disclosure on page 3, lines 29-32 of the present application, the embodiment of the multiple fluid distribution channels, which may be disposed between a port and the chamber, is supported. Therefore, the previous rejection of claims 2-11, 30-32, 42-47 under 35 U.S.C. 112, first and second paragraph are withdrawn. Additionally, in view of the arguments presented in the Appeal Brief, filed December 9, 2002, the previous 35 U.S.C. 102(b) and 103(a) over Juncosa *et al* (USP 6,225,109) have been withdrawn, since Juncosa *et al* do not clearly disclose a plurality of multiple fluid distribution channels disposed between an inlet and a single chamber. Therefore, the finality of the previous Office Action, mailed June 3, 2002, is withdrawn.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 2-11, 30-32, 42-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5 and 6, recite "the housing including a first set of multiple fluid distribution channels." The "housing 34" is defined within the specification as the member for receiving the substrate 10. Therefore, as can be seen from Figure 5 the housing member 34 simply holds the

substrate, no distribution channels are formed therein. Therefore is not clear as to how the housing includes a first set of multiple fluid distribution channels.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claim 5 is rejected under 35 U.S.C. 102(b) as being anticipated by Freeman (WO 96/30124).

Freeman teaches a method and package for performing polymer synthesis on a substrate array, e.g. slide or membrane (page 2, 3rd paragraph- page 3, 2nd paragraph) having multiple features, i.e. linker molecules. The package comprising a housing 82 having a chamber 86 formed by the substrate and housing, which is accessible through a first port 88. The housing includes a first set of multiple fluid distribution channels 89 disposed between the first port and the chamber. Additionally, Freeman teaches adding fluid through the first port such that fluid flow is directed by the multiple fluid distribution channels between the multiple different regions across the first side of the received substrate from the first port. Moreover, Freeman discloses wherein all of the channels are valved by a three-way valve mechanism 90 (page 16, last paragraph- page 17, 1st full paragraph, Figs.7A-B). Note: the phase "at least some of the fluid distribution channels are valved so as to be selectively closable or openable" does include all of the channels being valved, as defined by the instant specification, see page 3, lines 17-28, which

state "at lease some (including all) of the fluid distribution channels of at least one (including both) sets, are provided with a valve..."

6. Claims 2-6, 9, 30-31, 42 are rejected under 35 U.S.C. 102(e) as being anticipated by Austin *et al* (USP 5,427,663).

Austin *et al* teach a package for performing sorting and viewing multiple features on a substrate 22. The package comprising a housing 24 having a chamber 34 formed by the housing and the substrate. The chamber is accessible through a first port formed by the side walls 30, 31 and the coverslip 36, see loading area 66 (Figs. 1-2). The housing including a first set of multiple fluid distribution channels 54 disposed between the first port and the chamber. Additionally, Austin *et al* teach adding fluid through the first port such that fluid flow is directed by the multiple fluid distribution channels between the multiple different regions across the first side of the received substrate from the first port. Moreover, Austin *et al* disclose wherein all of the channels, formed by baffles, are micro- or capillary sized (column 11, lines 20-55, Fig. 4). The substrate can be exposed to irradiation, light illumination, etc. (column 23, lines 1-65). Note: it is well-known within the art that channels 10 microns in diameter exhibit capillary action to retain fluid. Additionally, the fluid flow width increases between the first port and the first set of distribution channels, see modified Figure 2 below, where Examiner has clearly marked the expansion area between the loading area 66 and the first set of distribution channels.

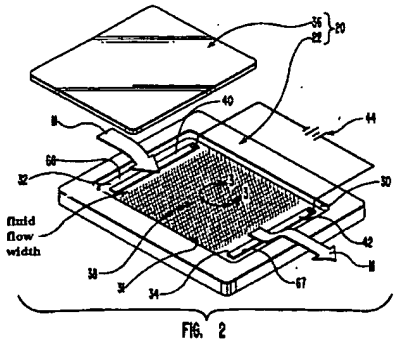

FIG. 2

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 6-9, 31-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman (WO 96/30124) in view of Jun *et al* (Valveless Pumping using Tranversing Vapor Bubbles in Microchannels).

Freeman as previously discussed above, do teach the use of valves to regulate the flow of

fluid within the distribution channels. However, they do not disclose the specific use of a bubble formation device comprising a bubble nucleating resistor. Jun *et al* teach the formation of a stationary bubble formed by boiling, via a heater, a liquid flowing through a micro-channel to serve as an obstruction against flow in the channel and therefore function as a valve (Introduction and Theory sections, Fig. 1).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to have included in the system of Freeman the bubble forming device, as taught by Jun *et al* . Valves often leak with use and affect long term reliability. In addition, valves are often formed of delicate components that must be carefully manufactured and installed for reliability. A bubble forming device requires no micro-mechanical moving parts, therefore reducing the need for valve components (abstract, introduction sections).

Freeman discloses the claimed invention except for explicitly stating the fluid distribution channels are capillary sized. However, Freeman does state the sealed chamber will have a volume between 50-300 microliters (page 5, 3rd paragraph), therefore it can be concluded the channels 86 are within the micrometer range. Note: it is well-known within the art that channels a few microns in diameter exhibit capillary action to retain fluid. It would have been obvious to one having ordinary skill in the art at the time the invention was made to the channels capillary sized, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Additionally, Freeman does show the fluid flow width increasing between the first port and the first set of distribution channels see modified Figure 7b below, where Examiner has

clearly marked the expansion area between the loading area 88 and the first set of distribution channels 89.

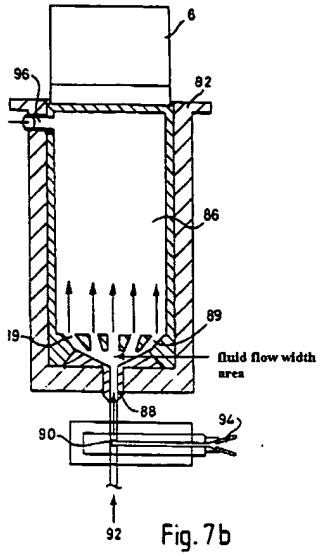

Fig. 7b

10. Claims 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman (WO 96/30124) in view of Besemer *et al* (USP 6,287,850).

Freeman is silent regarding the use of a self-sealing closure member over the first port. However, the use of a self-sealing closure member is considered conventional in the art, see Besemer. Besemer *et al* teach a method and apparatus for directing fluid sample across a nucleic array for promoting hybridization between a target in the fluid sample and probes on the array. The device of Besemer uses an inlet port in which a self-sealing septum is seated (Fig. 7). This insures that the seal is maintained even after the fluid is injected into the cavity since the pressure immediately forces the septum to reseal itself after the needle or other fluid injecting means is removed from the port. Thus an efficient and economical seal for retaining fluid in the cavity is provided.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to have included in the system of Freeman, the self-sealing septum, as taught by Besemer *et al* . Such a sealing means provides an efficient and economical seal for retaining fluid in the cavity (column 8, line 63- column 9, line 2).

11. Claims 43-44 are rejected under 35 U.S.C. 103(a) as being unpatentable Freeman (WO 96/30124) in view of Katoot *et al* (USP 6,184,030).

Freeman is silent regarding the step of communicating the result of the analysis to a location remote from the location of testing. However, communicating results obtained from analysis to a remote location is considered conventional in the art, see Katoot *et al* . Katoot *et al* teach a method using polymer films arranged in a matrix to provide the ability to perform multiple analyte determinations in a single sample. The data from the membranes may be displayed, printed, stored in a data storage means, input into a computer, sent to a remote data storage means or computer, or input into a trained neural network. Additionally, the system of Katoot *et al* may be configured to transmit the data to a remote location such as the office of a health care provider, health maintenance organization, etc (column 5 , line 56- column 6, line 3). This would aid the health care providers to evaluate data obtained from the patient samples and a form a diagnoses, prognoses, and develop a therapeutic strategy.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to have included in the system of Freeman , communication means, as taught by Katoot *et al* , in order to aid health care providers to evaluate data obtained from the patient samples and a form a diagnoses, prognoses, and develop a therapeutic strategy (column 12, lines 10-24).

12. Claim 45-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman (WO 96/30124) in view of Jun *et al* (Valveless Pumping using Tranversing Vapor Bubbles in Microchannels) as applied to claim 32 above, and further in view of Katoot *et al* (USP 6,184,030).

Freeman and Jun *et al* are silent regarding the step of communicating the result of the analysis to a location remote from the location of testing. However, communicating results obtained from analysis to a remote location is considered conventional in the art, see Katoot *et al.* Katoot *et al* teach a method using polymer films arranged in a matrix to provide the ability to perform multiple analyte determinations in a single sample. The data from the membranes may be displayed, printed, stored in a data storage means, input into a computer, sent to a remote data storage means or computer, or input into a trained neural network. Additionally, the system of Katoot *et al* may be configured to transmit the data to a remote location such as the office of a health care provider, health maintenance organization, etc (column 5 , line 56- column 6, line 3). This would aid the health care providers to evaluate data obtained from the patient samples and a form a diagnoses, prognoses, and develop a therapeutic strategy.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to have included in the system of Freeman, and Jun *et al* communication means, as taught by Katoot *et al* , for the reasons previously set forth above.

***Response to Arguments***

13. Applicant's arguments in the Appeal Brief, filed December 09, 2002, have been fully considered but they are not persuasive. However, the previous rejections under 35 U.S.C. 102(b) and 103(a) Winkler *et al* (USP 5,384,261) have been withdrawn. Additionally, in view of the

disclosure on page 3, lines 29-32 of the present application, the embodiment of the multiple fluid distribution channels, which may be disposed between a port and the chamber, is supported. Therefore, the previous rejection of claims 2-11, 30-32, 42-47 under 35 U.S.C. 112, first and second paragraphs is withdrawn. Additionally the previous 35 U.S.C. 102(b) and 103(a) over Juncosa *et al* (USP 6,225,109) have been withdrawn, since Juncosa *et al* do not clearly disclose a plurality of multiple fluid distribution channels disposed between an inlet and a chamber.

In response to the previous rejection of claims 5 under 35 U.S.C. 102(b) as being anticipated by Freeman (WO 96/30124). Applicant contends that Freeman do not teach at least some of the fluid distribution channels that are valved so as to be selectively closable or openable. Examiner does not agree, since Freeman shows the all the distribution channels being are valved by element 90. This element can be opened or closed (page 16, last paragraph- page 17, 1st full paragraph, Figs.7A-B). Examiner points out that the phase "at least some of the fluid distribution channels are valved so as to be selectively closable or openable" does not exclude all of the channels being valved, as defined by the instant specification, see page 3, lines 17-28, which state "at lease some (including all) of the fluid distribution channels of at least one (including both) sets, are provided with a valve..." (emphasis added).

With respect to the previous rejection of claims 7-8 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman (WO 96/30124) in view of Jun *et al* (Valveless Pumping using Tranversing Vapor Bubbles in Microchannels), Applicant argues that there is no motivation for combining Freeman with the bubble system of Jun *et al*. However, as previously pointed out, Jun *et al* is relied upon for the motivation and does disclose the advantage for using a bubble forming device, since this type of valve requires no micro-

mechanical moving parts, therefore reducing the need for valve components (abstract, introduction sections, Jun *et al*).

***Conclusion***

14. No claims allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Bex whose telephone number is (703) 306-5697. The examiner can normally be reached on Mondays-Thursdays, alternate Fridays from 6:00 am to 3:30 pm EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 308-4037.

The fax number for the organization where this application or proceeding is assigned is (703) 872-9310 for official papers prior to mailing of a Final Office Action. For after-Final Office Actions use (703) 872-9311. For unofficial or draft papers use fax number (703) 305-7719. Please label all faxes as official or unofficial. The above fax numbers will allow the paper to be forwarded to the examiner in a timely manner.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0661.

Kathryn Bex

P. Kathryn Bex
Patent Examiner
AU 1743
January 29, 2003

Jill Warden
Supervisory Patent Examiner
Technology Center 1700